

## REMARKS

The foregoing amendment and the remarks which follow are responsive to the initial, non-final Office Action mailed June 7, 2002 in relation to the above-identified patent application. In that Office Action, the Examiner objected to Claim 14 due to the recitation of the limitation "said change in axis" insofar as the same was set forth in the preamble of such claim, and not considered a positive disclosure of such element. To address such issue, the Examiner suggested amending the claim to positively disclose the phrase in question. With respect to the prior art, Claims 14-22 were rejected under 35 U.S.C. section 102(b) as being anticipated by PCT International Publication Number WO 94/00172. Claims 14 and 22 were further rejected under 35 U.S.C. section 102(b) as being anticipated Morrison (i.e., United States Patent Number 5,584,818). Such claims were further rejected under United Kingdom Patent Application Number 2252046 A.

By this amendment, Applicants have amended independent Claim 14, from which the remaining claims depend, to more clearly define the subject matter which they regard as the invention, as well as to distinguish the same from the cited prior art. More specifically, independent Claim 14 has been amended to indicate that the elongate needle having a change in axis formed along the length thereof as a positively disclosed element of the present invention, as had been suggested by the Examiner. Based upon such amendment, it should be clear that such claims are directed to needle protective devices produced in combination with specialty hypodermic needles and the like having a bend or change in axis formed along the length thereof, such as Huber needles and the like.

Moreover, Claim 14 has been amended such that the same indicates that the needle trap of the needle guard element is operative to cover the sharpened end of the needle, and need not

necessarily comprise a moveable needle trap transitional between retracted and operative configurations. Still further, Claim 14 has been amended to delete reference to a limiting apparatus insofar as the needle guard itself is engageable with the change in axis to limit forward advancement of the needle guard along the needle. Applicants respectfully submit that such amendment is supported in the specification, and depicted in Figure 141, which depicts an embodiment of a needle trap that simply covers the needle having the change in axis (as opposed to the moveable needle trap embodiment depicted in Figures 143 and 144), as well as a needle guard engaging the change in axis formed along the needle.

As for the remaining amendments made herein, Claim 15 has been amended such that the same is drawn to those embodiments of Applicant's protective devices which include a needle guard having a moveable needle trap transitional between retracted and operative configurations (i.e., Figures 143 and 144). Claim 16, 18 and 19 have been amended to reflect a dependency from amended Claim 15. Additionally, new Claim 23 has been added which reflects old Claim 15 verbatim, which is believed to simplify the arrangement of the claims in this case.

Along these lines, such amendments are believed to more clearly and distinctly claim the subject matter which Applicants regard as the invention, as well as to distinguish the same over the cited prior art. In this regard, each of the cited references, in sharp contrast to the present invention, are all utilized in connection with straight needle devices that extend along a single axis. See, e.g., Figures 9-12 and page 9, line 28 to page 10, line 19 PCT International Publication Number WO 94/00172; Figures 1-7 and page 1, second paragraph of United Kingdom Patent Application GB2252046A; and Figures 1-24 and column 3, line 30 to column 5, line 35 of Morrison. Clearly, the devices disclosed in each respective reference were never intended, much

less adapted, to be utilized with any type of needle having a change in axis formed along the length thereof. Indeed, Applicants respectively submit that the devices as disclosed in each of the aforementioned references would be completely incapable of extending along such a needle having a change in axis to safely capture the sharpened distal end thereof.

As is well-known, for anticipation to apply, all the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. See e.g., Studiengesellschaft Kohle m.b.H. v. Dart Industries, 220 USPQ 841, 842 (Fed. Cir. 1994). In this respect, a prior art reference cannot anticipate in terms of 35 U.S.C. section 102 unless every element of the claimed invention is identically shown in a single reference. In re Bond, 15 USPQ 2d, 1566, 1567 (Fed. Cir. 1990). In view of the amendment made to Claim 14, which positively recites a needle having a change in axis formed along the length thereof, coupled with a limiting apparatus engagable with the change in axis to limit the distance the needle guard of Applicant's invention can slidably travel upon said needle, it is believe that the rejection of the claims under 35 U.S.C. section 102(b) cannot be maintained.

Accordingly, Applicants submit that the claims of the present application, as amended, clearly and distinctly claim the subject matter which Applicants' regard as the invention and, as such, are in a condition for allowance. Early notice to that effect is respectfully requested. To the extent the Examiner has any questions or requires additional information regarding this application, or has any suggestions to expedite the resolution of any outstanding issues of which the Examiner is aware, the Examiner is invited to contact Applicants' counsel at the number listed below.

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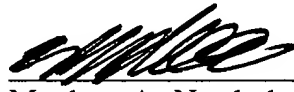
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made"

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 10/2/02

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 14, 15, 16, 18, 19, and 23 were amended as follows :

14. (Amended) A needle protective device comprising: ~~for use with~~
- (a) an elongate needle having proximal and distal ends and a change in axis formed intermediate said proximal and distal ends, <sup>1</sup>~~said needle protective device comprising:~~
  - (ab) a needle guard ~~slidably~~ mounted on the proximal end of said needle and slidable along a portion of said needle between said proximal end and said change in axis, said needle guard being engageable with said change in axis such that the distal advancement of said needle guard is stopped at said change in axis, said needle guard having a movable needle trap ~~that is transitional between a first retracted configuration and a second operative configuration wherein said needle trap traps~~ for covering said sharpened distal end of said needle; substantially coincident with when said needle guard engages said change in axis.
  - ~~(b) a limiting apparatus formed upon said needle guard and engageable with said change in axis formed upon said needle for limiting the distance said needle guard slidably travels upon said needle, said limiting apparatus being operative to engage with said change in axis coincident with when said needle trap transitions from said first retracted configuration to said second operative configuration.~~

~~15. The needle protective device of Claim 14 wherein said change of axis of said needle comprises a bend formed upon the length of said needle.~~

15. (Amended) The needle protective device of Claim 14 wherein said needle trap of said needle guard is transitional between a first retracted configuration and a second operative configuration wherein said needle trap covers said sharpened distal end of said needle.

16. (Amended) The needle protective device of Claim 14 15 wherein said ~~movable~~ needle trap is biased against said needle when said needle trap assumes said first retracted configuration.

18. (Amended) The needle protective device of Claim 14 15 wherein when said needle trap transitions from said first retracted configuration to said second operative configuration, said ~~limiting apparatus~~ needle guard subsequently engages with said change in axis.

19. (Amended) The needle protective device of Claim 14 15 wherein when said ~~limiting apparatus~~ needle guard is operative to engage with said change in axis, said needle trap subsequently transitions from said first retracted configuration to said second operative configuration.

20. (Amended) The needle ~~protector~~ protective device of Claim 14 wherein said change in axis defines a change in profile, said change in profile being engageable with said ~~limiting apparatus~~ needle guard.

21. (Amended) The needle ~~protector~~ protective device of Claim 20 wherein said change in profile defined by said change in axis comprises at least one outwardly-bulging sidewall portion.

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22. (Amended) The needle ~~protector~~ protective device of Claim 20 wherein said change in profile defined by said change in axis defines a recessed change in profile.

Please add the following new claim:

23. (New) The needle protective device of Claim 14 wherein said change of axis of said needle comprises a bend formed upon the length of said needle.

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